

**Texas Tech University Health Sciences Center**

**Recombinant DNA Biosafety Committee  
(RDBC)**

**POLICIES AND PROCEDURES MANUAL**

**Effective Date:  
10/1 /08**

## 1.0 Introduction

This Texas Tech University Health Sciences Center Institutional Recombinant DNA Biosafety Committee (“TTUHSC RDBC” or “RDBC”) Policies and Procedures Manual provides the TTUHSC research community with an overview of the federal regulations and institutional policies that govern the conduct of research utilizing recombinant DNA. A single RDBC will serve as the review committee for all relevant research utilizing recombinant DNA at all TTUHSC campuses and facilities in accordance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)<sup>1</sup>.

The RDBC Policy and Procedures Manual will be revised and updated as new guidelines, clarifications and/or other information becomes available. The RDBC, in conjunction with the TTUHSC Safety Services Office, will work with investigators and lab personnel to assist them in meeting federal and state requirements and TTUHSC policies and procedures related to the storage and use of recombinant DNA materials. Applications approved under any version of the RDBC Policies and Procedures may require modifications as federal, state and institutional rules change. All recombinant DNA research done at TTUHSC must be in compliance with these rules.

These RDBC Policies and Procedures are based on the following regulations, guidelines and TTUHSC policies:

- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), [http://www4.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Guidelines\\_Apr\\_02.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm)
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) published by the Centers for Disease Control and Prevention (CDC) and NIH. The BMBL is generally considered the standard for Biosafety, <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>
- Select Agents and Select Agent Toxins—HHS and CDC regulations 42 CFR 73 and USDA regulations 9 CFR 121
- Occupational Health and Safety Act (OSHA) Regulations,
- TTUHSC Operating Policy 75.10--Biological and Chemical Hazards Policy for Research Facilities and Personnel [www.ttuhschool.edu/hsc/op/op75/op7510.pdf](http://www.ttuhschool.edu/hsc/op/op75/op7510.pdf)
- TTUHSC Operating Policy 73.05 Research Involving Hazardous Chemical and Biological Materials, and Recombinant DNA, and [www.ttuhschool.edu/hsc/op/op73/op7305.pdf](http://www.ttuhschool.edu/hsc/op/op73/op7305.pdf)

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<sup>1</sup> The NIH Guidelines refer to this type of Committee as an Institutional Biosafety Committee (IBC). TTUHSC has chosen to establish a committee separate from its current IBC, which committee (the Recombinant DNA Biosafety Committee) will be responsible for reviews of recombinant DNA research in accordance with NIH Guidelines. TTUHSC Recombinant DNA Biosafety Committee Policies and Procedures  
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- TTUHSC Operating Policy 73.12 Possession and Use of Exempt Quantities of CDC Select Agent Toxins [www.ttuhs.edu/hsc/op/op73/op7312.pdf](http://www.ttuhs.edu/hsc/op/op73/op7312.pdf).

## 2.0 Definitions

**Annual Status Report Forms:** This refers to a single page form that the principal investigator is required to complete, sign and submit to the RDBC Administrator once each year for renewal of the initial Registration License. This form may also be used for an amendment to the initial Registration License or for termination of a recombinant DNA protocol at any time during the year. This form can be found as Attachment B to this manual.

**Biological Safety Officer (BSO):** A TTUHSC staff person who is trained as a Biosafety Officer and who is responsible for oversight of laboratory safety training, laboratory inspections, reviewing inventories and records and other duties as outlined in the NIH Guidelines, IV.B.c. The BSO will serve as a member of RDBC.

**Infectious Biological Agents:** Infectious biological agents include biological agents and biologically derived materials that present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Categories of potentially infectious biological materials include the following:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses),
- All human blood, blood products, tissues, and certain body fluids (excluding routine use of human blood and body fluid for clinical purposes).
- Cultured cells and potentially infectious agents these cells may contain, and
- Any Biosafety Level 2 or higher recombinant DNA materials.

**Laboratory Worker:** Any person, including, but not limited to faculty, staff, students and volunteers working in a laboratory in which biological or chemical materials are stored or used.

**Principal Investigator (P.I.):** The P.I. is the TTUHSC faculty member who has been designated as being responsible for the laboratory space, including supervision of research and staff therein. Such designation shall be done in writing by the Department Chair/Unit Supervisor. An alternate individual shall be designated as responsible when the principal investigator is unavailable or absent. An individual designated as an alternate PI must have adequate training and certification to serve in this capacity. He or she should be specifically named on the Registration form, signed by the original PI.

**Protocol:** A detailed summary initially provided by the P.I. in the document, “TTUHSC Institutional Recombinant DNA Questionnaire and Profile” (Attachment A to this manual) that is filed by the P.I. for all exempt and non-exempt use of recombinant DNA. It contains a description of the procedures involved with use of potentially hazardous materials, the location where the procedures will be performed, the techniques/procedures used to contain hazardous materials to protect personnel and the environment and a listing of approved personnel.

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**Recombinant DNA:** This is defined by current NIH Guidelines governing recombinant DNA research as either (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) molecules that result from replication of those described in (1) above. Also included are synthetic DNA segments that are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or pharmacologically active agent), since these are considered as equivalent to their natural DNA counterpart. If the synthetic DNA is not expressed *in vivo* as a biologically active polynucleotide or polypeptide product, it is EXEMPT from the NIH Guidelines.

**Research Laboratory:** Any laboratory (excluding accredited space occupied by the Laboratory Animal Resources Center) space occupied by the P.I. in which biological or chemical materials are used or will be stored. A research laboratory utilizing recombinant DNA requires RDBC protocol review and approval before such work may begin.

**Restricted access:** Limitation of access for only authorized personnel to an area because of the nature or type of use of hazardous materials stored in that area.

**Renewal/Amendment/Termination:** Document indicating any of three changes from submissions initially approved by the RDBC. All three are part of the Annual Status Report Form (See Attachment B). A renewal form is filed by the P.I. for continuation of a protocol previously approved by the RDBC. An amendment form is filed by the P.I. whenever there is a change in status of any of (1) the technical specifics of the protocol, (2) the laboratory space being utilized for the protocol or (3) the personnel involved in the protocol, as specified in the originally approved RDBC document submitted by the P.I., “TTUHSC Institutional Recombinant DNA Questionnaire and Profile”. A termination form is filed when the P.I. is no longer using or storing recombinant DNA.

**TTUHSC Institutional Recombinant DNA Registration (“Registration”):** This action is required of all P.I.s using recombinant DNA, and it is achieved by completing the “TTUHSC Institutional Recombinant DNA Biosafety Questionnaire and Profile” (See Attachment A). This form must provide a complete documentation of all recombinant DNA activities in the laboratory of the P.I. for the Chair of the RDBC, who then determines the status of such protocols as being either EXEMPT or NONEXEMPT from current NIH Guidelines Governing Use of Recombinant DNA. RDBC approval is formalized with a TTUHSC Institutional License for Use of Recombinant DNA.

**TTUHSC Institutional Recombinant DNA Research License (Registration License):** A document from the RDBC describing the authorized use of recombinant DNA in a research laboratory by authorized personnel, as well as any unique restrictions or limitations. The License is to be displayed prominently in the research laboratory, listing all approved personnel.

## **3.0 About the Institutional Recombinant DNA Biosafety Committee**

### **3.1 Purpose of the Institutional Recombinant DNA Biosafety Committee (RDBC)**

The purpose of the Texas Tech University Institutional Recombinant DNA Biosafety Committee (“TTUHSC RDBC” or “RDBC”) is to minimize risks to faculty, staff, students, volunteers, facilities, the community and the environment while storing and/or using recombinant DNA materials for purposes of teaching and research activities at TTUHSC. The RDBC also shares responsibility with the TTUHSC Office of Safety Services for compliance with relevant laws, regulations and guidelines pertaining to the receipt, use, storage and/or transfer of recombinant DNA materials. This Policies and Procedures manual outlines the processes that must be followed when obtaining, using, storing, transferring or destroying recombinant DNA and provides a review of the relevant regulatory requirements.

### **3.2 RDBC Scope and Authority**

These RDBC Policies apply to the receipt, use, storage, transfer and/or disposal of recombinant DNA materials as outlined in Section 2.0. They also apply to any activity and/or research involving recombinant DNA materials that:

- Is sponsored by TTUHSC (unless this is the only connection to TTUHSC)
- Is conducted by or under the direction of any employee or agent of TTUHSC (including faculty, staff, students, or volunteers) in connection with his or her responsibilities to TTUHSC, and/or
- Uses any property, facility or non-public information belonging to or under the control of TTUHSC.

### **3.3 RDBC Registration with National Institutes of Health**

In accordance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) the TTUHSC RDBC is registered with the NIH Office of Biotechnology Activities (OBA). An annual report is filed with OBA by the RDBC Administrator. The annual report includes an updated list of RDBC members and a “biosketch” of each member. The OBA is also notified of any changes in RDBC membership between annual reports by the RDBC Administrator.

### **3.4 RDBC Responsibilities**

The RDBC’s responsibilities are to:

1. Develop institutional policies for the safe use, handling, and storage of recombinant DNA materials,
2. Advise the institution and investigators on policies involving recombinant DNA materials,
3. Review all protocols involving recombinant DNA in accordance with NIH Guidelines.

4. Advise the Laboratory Animal Resource Center on safe practices for work involving the use of recombinant DNA materials,
5. Certify, as required to granting agencies, that facilities, procedures and practices, as well as the training and expertise of personnel handling recombinant DNA materials, have been reviewed and approved by the RDBC,
6. Supervise the institutional educational programs on the transfer, storage and/or use of recombinant DNA materials,
7. Adopt emergency plans covering accidental spills and personnel contamination resulting from use, storage or handling of recombinant DNA; and
8. Implement corrective action, including lab closure, when necessary to safeguard employees, the public and the environment.

The RDBC is also responsible for initially and periodically reviewing Registrations for possession and/or use of recombinant DNA materials for compliance with NIH Guidelines, the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual and Select Agent and Select Agent Toxins regulations, as applicable. As part of the review process, and in conjunction with the BSO and TTUHSC Office of Safety Services, the RDBC shall:

- Conduct an independent assessment of the containment levels as required by Section II-A-3 of the NIH Guidelines,
- Conduct an assessment of the facilities, procedures, practices, training and expertise of personnel involved in research with recombinant DNA materials, and
- Ensure compliance with all surveillance, data reporting and adverse event reporting requirements set forth in the NIH Guidelines.

### **3.5 RDBC Membership**

The RDBC is composed of at least five members that collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and identify any potential risk to public health or the environment. All members, including the Chair, shall be appointed by, serve at the discretion of, and report to the EVPR. Recommendations for appointees may be made to the EVPR by current RDBC members or administrative staff. In general, appointments will be made effective September 1 of each year.

The appointed members will represent each of the TTUHSC campuses at which research with recombinant DNA materials takes place. Attempts will be made to include representatives from each of the TTUHSC Schools. The composition of the RDBC shall consist of:

- At least one or more individuals with expertise in each of the following areas: animal containment principles, genetics, micro-organisms, recombinant DNA technology, biological safety and/or physical containment,
- At least one member representing the laboratory technical staff,
- Two committee members who are not affiliated with TTUHSC (including family members) who represent the interests of the west Texas area with respect to health and protection of the environment, and

- The TTUHSC Biological Safety Officer.

An individual may meet more than one of the above criteria.

At least one individual with expertise in plant, plant pathogens, or plant pest containment principles will be appointed to the RDBC as a voting member, if ever any TTUHSC researchers wish to begin conducting recombinant DNA research that requires Institutional Recombinant DNA Biosafety Committee (RDBC) approval in accordance with NIH Guidelines, [Appendix P](#), *Physical and Biological Containment for Recombinant DNA Research Involving Plants*.

Appointment to the RDBC may be rescinded at the sole discretion of the EVPR. Removal of members will generally be for cause, but not, in any case, for purposes of retaliation or for unconstitutional reasons. Members may also be removed and replaced for more than three unexcused absences during a fiscal year.

### 3.5.1 RDBC Chair

The RDBC Chair is appointed by the EVPR from among the RDBC members. The RDBC Chair shall be an experienced scientific investigator with regard to issues related to biosafety, especially as it pertains to working with recombinant DNA. The RDBC Chair shall make determinations of exempt protocols, preside over the RDBC meetings to review nonexempt protocols, serve as the contact for all regulatory agencies and act as a liaison between the academic community and the RDBC. The RDBC Chair shall appoint a Vice-Chair to act in his/her absence. The Vice-Chair and designated RDBC members shall serve as primary reviewers for all non-exempt recombinant DNA proposals submitted to the RDBC, as preliminarily determined by the RDBC Chair. The RDBC Chair is responsible for making sure that RDBC members are appropriately trained.

### 3.5.2 The Biological Safety Officer (BSO)

The BSO has the following duties:

- Conduct periodic inspections of research laboratories to verify that laboratory standards are vigorously followed;
- Report to the RDBC and EVPR any significant problems, violations of the NIH Guidelines and any significant research-related accidents or illnesses, related to the use or storage of recombinant DNA of which the BSO becomes aware of unless the PI has already filed a report;
- Provide advice on laboratory security; and
- Provide technical advice to PIs and the RDBC on research laboratory safety procedures.

### 3.5.3 Consultants

The TTUHSC veterinarian, a plant scientist or other specialists may be consulted, if and when needed in special circumstances, although these persons will not vote unless formally appointed as full members of the RDBC. The RDBC may also invite consultants knowledgeable in

community attitudes and the environment to its meetings as necessary to assist in any review, but such consultants may not vote.

### **3.6 RDBC Meetings**

The Committee will meet on the first Tuesday of each month or as necessary as scheduled by the RDBC Chair in months during which there is business to conduct. At a minimum, the Committee shall meet once every fiscal year. Prior to each meeting, all voting RDBC members shall receive copies of Registrations and related materials for all nonexempt recombinant DNA research, along with a copy of the agenda and draft minutes from the previous meeting.

Special meetings may be called by the RDBC Chair, or any member of the RDBC. Except in cases of emergency, at least three days notice shall be given.

#### **3.6.1 Open Meetings**

Prior notice of each meeting of the RDBC shall be appropriately posted for the public. Except where necessary to protect privacy and proprietary interests, the RDBC meetings shall be open to the public.

#### **3.6.2. Quorum**

A majority of the voting members must be present to conduct the business of the RDBC, except for expedited reviews. The final approval or disapproval of registration of each agenda item not receiving expedited review requires a majority vote of RDBC members present and voting. If a quorum is lost at any time during the meeting, no further action shall be taken by the RDBC until a quorum is attained.

#### **3.6.3 Attendance**

Members are expected to attend a majority of RDBC meetings. Anticipated absences from an RDBC meeting should be communicated to the RDBC Chair and the RDBC Administrator at least 24 hours before a meeting.

#### **3.6.4 Conflict of Interest**

The TTUHSC RDBC is bound to the policies set forth in TTUHSC OP 10.08, Ethics Policy and TTUHSC OP 73.09, Conflict of Interest in Research. Failure of any RDBC members to comply with these policies may result in suspension of membership on the committee. An RDBC member who has or expects to be engaged, or has a direct financial interest, in a particular protocol may not be involved in the review or approval of that project, except to provide information as may be requested by the RDBC.

RDBC members shall leave the meeting during the discussion and voting on research in which any conflict exists. Their absence will be noted in the RDBC meeting minutes. A conflict of interest includes, but is not limited to:

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- Involvement in the research as principal investigator or co-investigator,
- Personal relationship with the PI (such as spouse) or strong positive or negative interactions that may be perceived as a possible conflict, and
- A personal belief system that would preclude acceptance of any research in a particular area even though permitted under existing regulations or policies.

### **3.7 Meeting Minutes**

Minutes of RDBC meetings shall be completed in sufficient detail to demonstrate the following:

- Date, time and location of the meeting,
- Attendance at the meetings and presence of a quorum,
- Actions taken by the RDBC regarding each agenda item,
- Notation of members who were not present during deliberations and voting due to a conflict of interest,
- The basis for requiring changes or disapproving any initial review or renewal of any research protocol, and
- Thorough discussion of research related issues and their resolution.

### **3.8 RDBC Records**

#### **3.8.1 Access to Documents:**

Certain RDBC documents are considered privileged and confidential records, not subject to disclosure, except to authorized TTUHSC representatives and federal regulatory officials. However, in accordance with the NIH Guidelines, TTUHSC shall, upon request, make available to the public all RDBC meeting minutes and any documents submitted to or received from funding agencies, which the federal funding agencies are required to make available to the public. If public comments are made on RDBC actions, the RDBC Chair shall forward both the public comments and the RDBC response to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985.

#### **3.8.2 File Composition**

The RDBC Office files shall be maintained, either electronically or in hard copy, in a manner that reflects a complete history of all RDBC actions related to review and approval of a protocol, including renewal, amendment and termination forms.

#### **3.8.3 Document retention**

The RDBC Administrator shall retain the following documents for at least three years.

- RDBC meeting agendas and minutes,
- RDBC Questionnaires (also known as initial Registration Forms) and attachments,

- RDBC Renewal, Amendment and Termination forms and attachments, and
- RDBC membership roster.

The RDBC shall retain copies of annual NIH/OBA Registrations, annual reports, and notices of new members until such time as the RDBC is no longer registered with NIH/OBA.

### **3.9 Reporting to NIH**

The RDBC shall report any significant problems with or violations of the NIH Guidelines or any significant research-related accidents or illnesses related to recombinant DNA to the EVPR and the TTUHSC Research Integrity Office within 30 days. Unless a report of the problem has already been filed by the Principal Investigator, these reports will be sent by the EVPR to NIH/OBA at the following address:

Office of Biotechnology Activities  
National Institutes of Health  
6705 Rockledge Drive, Suite 750, MSC 7985  
Bethesda, MD 20892-7985

### **3.10 Compliance Oversight and Corrective Action**

The RDBC has the authority to address non-compliance with these procedures, the NIH Guidelines, the BMBL, and Select Agents and Select Agent Toxins regulations. Non-compliance can result in the RDBC taking one or more of the following actions:

- Lab closure,
- Suspending the use of the recombinant DNA materials,
- Confiscation/Destruction of the recombinant DNA materials, and
- Other actions necessary to safeguard employees, the public and the environment.

The EVPR and the TTUHSC Research Integrity Office shall be notified of these actions and the reasons for them. The Principal Investigator shall be notified in writing by the RDBC Chairperson of the actions to be taken, the reasons for the actions, and corrective actions recommended by the RDBC. Investigators or labs who have been subject to corrective action by the RDBC must provide a corrective action plan to be reviewed and approved by the RDBC before any research can resume.

## **4.0 Principal Investigator's Responsibilities**

### **4.1 Risk Assessment**

A Principal Investigator who wishes to obtain, possess and/or use recombinant DNA materials must make an initial risk assessment of the biohazardous materials based on the Risk Group (RG) of the agent in order to establish the proper physical and biological containment level. This risk assessment shall be in accordance with Section II-A of the NIH Guidelines. "Risk" implies

the probability that harm, injury, or disease will occur. The primary focus of a risk assessment is to prevent or reduce the risk of laboratory-associated infections or accidental or unintentional release of potentially biohazardous agents into the environment. The initial risk assessment is made from review of Appendix B in the NIH Guidelines Governing Recombinant DNA Research.

#### 4.1.1 Risk Group Classification

Agents are classified into four Risk Groups according to their relative pathogenicity for healthy adult humans as follows:

- **Risk Group 1 (RG-1)** agents are not associated with disease in healthy adult humans,
- **Risk Group 2 (RG-2)** agents are associated with human disease which is *rarely* serious and for which preventive or therapeutic interventions are *often* available,
- **Risk Group 3 (RG-3)** agents are associated with *serious or lethal* human disease for which preventative or therapeutic interventions *may be* available, and
- **Risk Group 4 (RG-4)** agents are *likely to cause* serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

The NIH Guidelines, Appendix B (“Classification of Human Etiologic Agents on Basis of Hazards” [http://www4.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_B.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm)) serves as a reference when assessing the risk of a particular biohazardous agent.

#### 4.1.2 Consideration of Agent Factors and Intended Research Use

The agent’s Risk Group is one component in assigning the appropriate level of physical and biological containment to reduce the risk of exposure to an agent. In addition, the following factors should be considered in assessing the risk and determining the level of physical and biological containment for the agent(s):

- |  |   |
|--|---|
| • Pathogenic virulence   | • Origin of the material  |
| • Operations in proposed research                              | • Data from animal studies  |
| • Route of transmission (e.g. parenteral, airborne, ingestion) | • Availability of immunization or vaccine or treatment                              |
| • Stability of agent   | • Gene product effects (e.g., toxicity, physiological activity , and allergenicity) |
| • Infectious dose of agent/communicability                     |   |
| • Concentration  |   |

When working with DNA of pathogens, any strain that is known to be more hazardous than the wild type parent (original) strain should be considered for handling at a higher containment level. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify through an RDBC review for a reduction of the containment level compared to the Risk Group assigned to the parent strain. See NIH Guidelines Section V-B, Footnotes and References of Section I-IV.

In addition to the above factors, consideration should be given to the types of manipulation planned for some higher Risk Group agents. Also, the PI should consult the Occupational and Health Administration (OSHA) regulation (29 FCR 1910.1030), and OSHA publication 3127 (1996 revised) when working with HIV, HBV, blood-borne pathogens, other blood-contaminated clinical specimens, body fluids, and tissues from all humans, or from HIV- or HBV-infected or inoculated animals.

## **4.2 Biosafety Level**

The Principal Investigator must also make an initial assessment of the proposed biosafety level for biohazardous agents with which s/he will be working. The final assessment of risk, based on the agent's Risk Group and other risk factors, should be utilized to determine the appropriate Biosafety Level (BL-1 to BL-4). The Biosafety Level describes the degree of physical and/or biological containment required to confine biohazardous materials and to reduce the potential for exposure of laboratory workers, person outside the laboratory, and the environment. Physical containment can be divided into two categories: (i) a set of standard practices that are generally used in microbiological laboratories; and (ii) special procedures, equipment, and laboratory installations that provide physical barriers that are applied in varying degrees according to the estimated biohazard. A third category of containment is the application of highly specific biological containment. The NIH Guidelines, Appendix I: Biological Containment, provides additional information.

**Note: TTUHSC does not have any laboratories certified for BL-4. Therefore, no use or possession of recombinant DNA materials requiring BL-4 is allowed in any TTUHSC laboratory.**

The following is a general description of the acceptable biosafety levels, which are described in more detail in the NIH Guidelines, Appendix G: Physical Containment.

**Biosafety Level 1 (BL-1):** This containment level is suitable for work involving materials of a minimal potential biohazard to laboratory personnel and the environment.

**Biosafety Level 2 (BL-2):** This containment level is suitable for work involving materials of a moderate potential biohazard to personnel and the environment. The biohazardous materials are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

**Biosafety Level 3 (BL-3):** This containment level is suitable for work involving biohazardous materials that are associated with human disease which may have serious or lethal consequences or that has a potential for aerosol transmission.

**Biosafety Level 4 (BL-4)**—This containment level is suitable for work involving biohazardous materials that pose a high risk of life threatening disease, aerosol transmission, or related agents with unknown risk of transmission.

These biosafety levels are determined by various criteria including pathogenicity, route of transmission, stability, infectivity, infectious dose, concentration, origin of sample, and availability and effectiveness of vaccine.

There are specific biosafety levels for work with biohazardous agents involving plants or animals. Additional information can be found in the NIH Guidelines, Appendices P (plants) and Q (animals) as well as the BMBL.

The Biosafety Level may be equivalent to the Risk Group classification of the agent, or it maybe raised or lowered based on a comprehensive risk assessment. If you have any questions regarding the risk assessment or appropriate containment level, you may consult with the RDBC Committee Chair, the TTUHSC BSO, or any member of the RDBC. Except for certain, defined recombinant DNA experiments whose biosafety level is established by the NIH, the RDBC makes the final determination as to the appropriate Biosafety Level.

### **4.3 Other Principal Investigator Responsibilities**

Each Principal Investigator is responsible for compliance with all federal regulations and institutional policies when conducting research involving biohazardous or chemically hazardous materials and with the NIH Guidelines when conducting research with recombinant DNA. The Principal Investigator is responsible for ensuring that reporting requirements under the NIH Guidelines for recombinant DNA are fulfilled. Additional information and guidance can be found in the NIH Guidelines or by contacting the RDBC Chair.

#### 4.3.1 General Responsibilities

A Principal investigator shall:

- NOT initiate or modify any research involving recombinant DNA materials subject to RDBC approval under these RDBC Policies or NIH Guidelines until the research or proposed modification has been approved by the RDBC. This includes any changes to procedures, location or personnel working on a previously approved protocol,
- Immediately report any significant problems or any significant research-related accidents and illnesses **in writing** to the BSO, the RDBC Chairperson, the EVPR, and any other TTUHSC committee that has reviewed and approved the research activity,
- Be adequately trained in good laboratory practice regarding the use of recombinant DNA materials,
- Provide and maintain documentation of material-specific training to staff, students, and volunteers related to protocols registered through the RDBC,
- Adhere to TTUHSC RDBC approved emergency plans for handling accidental spills and personnel contamination, and
- Comply with shipping requirement for recombinant DNA materials. For technical guidance, Principal Investigators may consult the NIH Guidelines, Appendix H, “Shipment for recombinant DNA” or contact the TTUHSC Office of Safety Services.

#### 4.3.2 Prior to Initiation of Research involving Recombinant DNA Materials:

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The NIH Guidelines are applicable to all recombinant DNA research conducted in the United States, regardless of funding source. All recombinant DNA research that takes place at a TTUHSC facility must comply with NIH Guidelines. Therefore, any Principal Investigator wishing to conduct research utilizing recombinant DNA at TTUHSC must first meet with the Chair of the RDBC to ensure that the research or proposed modification meets all requirements of the NIH Guidelines. The Principal Investigator and RDBC Chair shall determine whether the experiments are covered by NIH Guidelines, Section III-F, *Experiments that Require RDBC Notice Simultaneous with Initiation*, and ensure that appropriate procedures are followed.

Prior to initiation of research involving recombinant DNA materials, as appropriate for the materials being used, each Principal Investigator shall:

- Obtain approval from the RDBC (and other relevant TTUHSC review committees, such as the IRB, IACUC, Radiation Safety Committee, etc.) PRIOR to initiating or modifying any research activity.
- Review applicable guidelines and regulations and become familiar with the safety procedures and requirements related to the materials involved in the research activity,
- In conjunction with Safety Services, ensure that all research personnel have received training on Laboratory Safety Essentials,
- Instruct laboratory personnel on the potential hazards associated with the research, the necessary precautions to prevent exposures and the exposure evaluation procedures,
- Instruct and train laboratory staff in practices and techniques required to ensure safety and the procedures for dealing with laboratory accidents,
- Inform laboratory staff of where and how to obtain emergency medical treatment for any laboratory accidents which may occur, and

#### 4.3.3 During the Conduct of Research involving Recombinant DNA Materials:

As appropriate for the materials being used, each Principal Investigator shall:

- Limit or restrict access to the laboratory when work with the recombinant DNA material is in progress,
- Provide personal protective equipment required for work with specific hazardous material. See the TTUHSC Chemical Hygiene plan and the product MSDS for guidance,
- Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the BSO, the RDBC Chairperson, and the EVPR. These officials will determine whether a report to the NIH Office of Biotechnology Activities is necessary,
- Report any adverse events in connection with the use of recombinant DNA materials in writing to the RDBC Chair, and

- Be proactive in monitoring the environment to prevent work errors or conditions that may lead to adverse events or significant problems with containment practices.

#### 4.3.4 Experiments Requiring Submission to NIH/OBA

The Principal Investigator, with assistance from the RDBC Committee Chair shall:

- Submit information to the NIH Office of Biotechnology Activities for certification of new host-vector systems (NIH Guidelines, Section IV-B-7-b-(1)),
- Petition NIH/OBA , with notice to the RDBC, for proposed exemptions to the NIH Guidelines (NIH Guidelines, Section IV-B-7-b-(2)),
- Petition NIH/OBA with concurrence of the RDBC, for approval to conduct experiments specified in NIH Guidelines Sections III-A-1, *Major Actions Under the NIH Guidelines* and Section III-B, *Experiments that Require NIH/OBA and Institutional Biosafety Committee (RDBC) Approval Before Initiation*, and
- Petition NIH/OBA for determination of containment for experiments requiring case-by-case review (NIH Guidelines, Section III-B), or which are not explicitly covered by the NIH Guidelines.

#### 4.4 Reporting Laboratory Accidents and Exposures

All adverse events, illnesses, or significant accidents leading to or potentially leading to an illness or any event that is environmentally dangerous to humans, animals or plants, must be reported in writing within 24 hours to the RDBC Chair, the BSO and the EVPR. The written report must include the following information:

- Principal Investigator's name, campus, department, and laboratory location,
- Name and description of the recombinant DNA material(s) involved,
- Name(s) of personnel involved,
- A description of the adverse event or significant research related accident/illness, and
- A description of the immediate corrective actions taken and any long-term actions which would prevent future occurrences.

After the report has been received and reviewed, a decision will be made as to whether the NIH/OBA must be notified. A summary of the report will be distributed to RDBC members for review. The RDBC will consult with the Principal Investigator to determine what further actions, if any, are to be taken.

#### 4.5 Access to Laboratories

Principal Investigators shall allow access to their laboratories to members of the RDBC conducting business on behalf of the RDBC, to the BSO, to the EVPR, or to the Director of Safety Services for routine or for-cause laboratory inspections. In the event of a significant laboratory accident or exposure, additional personnel shall be given laboratory

access. This may include, but is not limited to, law enforcement or medical personnel as necessary to ensure the safety of faculty, staff, students or the environment.

## **5.0 Protocol Registration and RDBC Review**

### **5.1 RDBC Protocol Registration**

A Principal Investigator who wishes to possess or use recombinant DNA materials shall submit the completed “TTUHSC Institutional Recombinant DNA Biosafety Questionnaire and Profile” (Attachment A to this manual) to the RDBC Administrator. No one shall obtain or use any materials subject to registration with the RDBC until the registration request has been approved by the RDBC, or after approval of the amendment form described below, if it applies to an existing Registration previously approved by RDBC. Modification of any previously approved Registration shall not be put into effect until the modification has been approved by the RDBC in accordance with TTUHSC policy.

### **5.2 Principal Investigator and Research Staff Laboratory Safety Education**

All Principal Investigators, co-investigators and research staff members are required to receive training regarding laboratory safety prior to conducting any work in any TTUHSC laboratory. The currently approved training is titled Laboratory Safety Essentials. It is an online training course which can be accessed from the following website: <http://www.ttuhs.edu/admin/safety/training.aspx#>.

### **5.3 Submitting an Initial Registration for RDBC Review**

The TTUHSC RDBC Registration Form, “TTUHSC Institutional Recombinant DNA Biosafety Questionnaire and Profile”, can be found as Attachment A to these policies and procedures. The responses to the Registration Form must be typed and each response must be completed in its entirety. The completed Registration Form with signatures must be delivered to the RDBC Administrator no less than two weeks prior to the first Tuesday of the month. Incomplete Registration Forms will be returned to the Principal Investigator for completion.

#### **5.3.1 Initial Review of the Questionnaire**

Initial Registration Forms that are complete and received by the deadline stated above will be forwarded to the RDBC Chair who shall review the information to determine whether or not the use of the recombinant DNA is exempt from further RDBC review in accordance with the NIH Guidelines. If the RDBC Chair determines that the use of the recombinant DNA is exempt under the NIH Guidelines (Section III-F), the RDBC shall notify the Principal Investigator and report this information at the next scheduled RDBC meeting. If the RDBC Chair determines that the use of recombinant DNA is nonexempt under the NIH Guidelines, the RDBC Chair shall forward the Registration Form and all attachments to a designated member of the RDBC (the Primary Reviewer) and the BSO to present at the next scheduled RDBC meeting. The RDBC Chair shall also schedule a meeting of the RDBC in accordance with these policies to review the Registration Form.

**Note: Registration and approval of the exempt status of any exempt recombinant DNA use by the RDBC Chair is required prior to the initiation of the research.**

### 5.3.2 Review of Nonexempt Use of Recombinant DNA

The Primary Reviewer and BSO will make every effort to contact the Principal Investigator regarding the need for clarifications or corrections to the application **prior to** the RDBC meeting in order to expedite the review process.

The Primary Reviewer will review the application for completeness, with a special emphasis on safety concerns relevant to the application. This will include a review of the materials to be used, the investigator's plans for safe use and disposal of the materials, and a brief review of the studies in which the materials will be used. The BSO or designee will review the application to verify the laboratory license and that appropriate training has been completed by all laboratory personnel.

At the RDBC meeting, the Primary Reviewer will present a summary of the Registration Form and then open the meeting up for discussion. Once the review is complete, the RDBC will vote on the application.

The RDBC vote on a new application can result in one of the following actions:

- Approval without restriction
- Contingent Approval (minor corrections/clarifications are required to be submitted to the RDBC Chair prior to final approval)
- Table the decision pending receipt of additional information or major corrections/clarifications to the application
- Disapproval

The Principal Investigator will be notified of the RDBC's decision within 14 business days of the RDBC meeting. If the Principal Investigator is required to provide additional information, corrections or clarifications, replies are due to the RDBC within 30 days of the written notice to the PI unless otherwise specified. If a PI's response will be delayed due to extenuating circumstances, arrangements should be made with the RDBC Chairperson or RDBC Administrator.

### 5.3.3 RDBC Disapproval of a protocol

An RDBC vote to disapprove a Registration for use of recombinant DNA indicates that there shall be no further review of the Registration. The Principal Investigator shall be notified in writing within 14 days of any RDBC vote to disapprove a Registration. The EVPR shall be copied on the correspondence to the PI.

The written RDBC disapproval notification to the PI will include reasons for the decision of the RDBC. The PI may request reconsideration of the decision of the RDBC in writing within 10 days of the date of notice. The PI shall provide a rationale for the request to reconsider and any other relevant supporting documentation to the RDBC

Chair who shall schedule a meeting of the RDBC. The PI may also address the RDBC in person at the next scheduled RDBC meeting. The RDBC shall notify the PI in writing of its decision after reconsideration and the reasons for its decision. No further request for reconsideration by the PI is permitted following the final decision by the RDBC made on reconsideration.

#### **5.4 Modifications to Approved Registrations**

Principal Investigators shall not initiate or implement any changes or modifications of RDBC approved registrations without the prior review and approval of the RDBC. This includes, but is not limited to, a change in the types of recombinant DNA materials, changes in personnel, or changes that increase the risk of the project and/or the Biosafety Level. An Amendment form (Attachment B to this document) must be completed, signed and submitted by the PI to the RDBC Administrator at least two weeks prior to the first Tuesday of the month.

Minor changes to the protocol (typically personnel changes for which appropriate training has been verified and location changes) may be approved by expedited review by the RDBC chair and acknowledged prior to the next scheduled RDBC meeting. RDBC members will be notified of these minor modifications at the next scheduled RDBC meeting but no discussion or vote will be required for minor changes approved by the RDBC Chair via an expedited review.

Major changes to the protocol (including changes in recombinant DNA materials or changes in principal investigator) require review and approval at a convened meeting of the RDBC. Investigators who need to add materials from their previously approved Registration must complete an addendum form in addition to the Amendment form described above. Once completed, the correct renewal or amendment form should be delivered to the RDBC Administrator no less than two weeks prior to the first Tuesday of the month.

#### **5.5 Continuing Review of Approved Registrations and Notice of Termination**

##### **5.5.1 Annual status reports**

Principal investigators who wish to continue their activity with hazardous materials for more than one year will be required to submit an annual status report to the RDBC for review prior to the anniversary date of the Registration approval. Annual status report forms are required for principal investigators who want to retain their Registration for another year. The principal investigator is responsible for completing the form and returning it to the RDBC Administrator before the anniversary date. The deadline for return to the RDBC Administrator is indicated on the annual status report. The Annual Status Report Form can be found as Attachment B to this document.

##### **5.5.2 Three year renewal process**

All continuing RDBC-approved protocols require a **detailed renewal** after three years, i.e., a new Registration Form (TTUHSC Institutional Recombinant DNA Biosafety TTUHSC Recombinant DNA Biosafety Committee Policies and Procedures Version 10.08

Questionnaire and Profile—See Attachment A to these Policies) must be completed, signed and returned to the RDBC Administrator. Approximately one month before the end of the 3<sup>rd</sup> Registration year, the PI may receive a courtesy notice of the upcoming required registration, a web address to the Registration Form and a deadline on when to return the completed Registration to the RDBC Administrator. Requirements for Registration renewal are identical to those for initial review of the protocol. It is the responsibility of the principal investigator to be aware of this requirement and to submit the appropriate documentation.

### 5.5.3 Termination of a protocol/registration

Principal Investigators who will be leaving TTUHSC or who will no longer be using recombinant DNA materials are required to notify the RDBC Administrator in writing of their intent to terminate their Registration(s), using the Annual Status Report form (Attachment B). The investigator should also work with the RDBC and Safety Services to ensure that any recombinant DNA materials in the lab are properly destroyed or transferred to a different TTUHSC laboratory as approved by the RDBC. The RDBC will be informed of terminations at the next regularly scheduled RDBC meeting. Investigators who are closing a laboratory for any reason should also refer to the TTUHSC Lab Close-Out Policy, TTUHSC OP 73.10.

### 5.5.4 Full or Partial Transfer of recombinant DNA Materials to another laboratory

Principal investigators who wish to transfer recombinant DNA materials to another faculty member must notify Safety Services of their intent to transfer the materials. The investigator who is to **receive** the transferred materials is responsible for submitting an amendment and appropriate addendum to the RDBC for review and approval prior to the transfer of the materials. No recombinant DNA materials shall be transferred until RDBC approval has been granted for the submission(s) related to the requested transfer. Investigators may also need to refer to HSC OP 73.02 Ownership and Transfer of Externally Sponsored Projects and Research Records.

ATTACHMENT A—INITIAL PROFILE—2 PAGES  
**TTUHSC INSTITUTIONAL RECOMBINANT DNA BIOSAFETY  
 QUESTIONNAIRE AND PROFILE**

For review by Recombinant DNA Biosafety Committee (RDBC)

*Please submit an original plus one copy (2 total) of this completed form to the OFFICE OF SPONSORED PROGRAMS (OSP), HSC LUBBOCK STOP 6271*

**PRINCIPAL INVESTIGATOR:            CAMPUS:**

**SCHOOL:                                  DEPARTMENT:**

**CONTACT NO.: EXT.                  FAX NO.:**

**E-MAIL: PROJECT TITLE:**

**A. PROVIDE A BRIEF RESEARCH SUMMARY OF THE PROPOSED STUDY (Please use no more 100-150 words. (Write so an informed lay person can understand what you plan to do, how and why. Also, attach the technical Abstract & Specific Aims page from the protocol or grant application.)**

Principal Investigator Signature	Date	Department Chair Signature	Date
I certify that the principal investigator is knowledgeable in this area and will employ sound scientific methods in the conduct of this research.			

IF MORE THAN ONE DEPARTMENT IS INVOLVED IN THIS STUDY:

Co-Investigator Signature	Date	Department Chair Signature	Date
Co-Investigator Signature	Date	Department Chair Signature	Date

**GO TO SECTION B - DO NOT WRITE BENEATH THIS LINE - FOR COMMITTEE USE ONLY**

APP NO. \_\_\_\_\_ Date RDBC Received: \_\_\_\_\_

APPROVAL AND MINIMUM BIOLOGICAL AND PHYSICAL CONTAINMENT REQUIRED FOR THE PROPOSED STUDY AT TTUHSC UNDER CURRENT NIH GUIDELINES FOR RECOMBINANT DNA RESEARCH (Reference Source: Federal Register Vol. 59, pp. 34496, July 5, 1994.

- \_\_\_\_ EXEMPT from current NIH guidelines  
 \_\_\_\_ NON-EXEMPT from current NIH guidelines
1. Physical containment required:
  2. Biological containment required:

**CONTINUING REVIEW DUE:**

(approximately)	Signature of Authorized RDBC Representative	Date Approved
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**B. MATERIALS & PROCEDURES INVOLVED IN THIS PROPOSED STUDY.** (Please be brief, but complete. Append additional pages ONLY if necessary.)

1. What are the sources (organisms, tissue, characterized clone, etc.) of the DNAs to be cloned and the nature of the inserted DNA sequences, e.g., a genomic library, a cDNA library or subcloning a previously purified DNA? (Provide a specific reference for all published recombinant DNA materials to be used.)

2. Which vectors and hosts (prokaryotic and eukaryotic) will be used? (List all the above which will be used and explain briefly how. If the vector is a special construction, describe it, and provide a literature reference for it and its origin with respect to the NIH approved vectors, and answer similarly for the host..)

a. Prokaryotic Vector =

Host =

b. Eukaryotic Vector =

Host =

3. Will expression be attempted? YES  NO  If YES, what are the circumstances, and what RNAs and/or what proteins will be produced? (Describe the constructions and how these will be used for expression.)

4. Will recombinant DNA be used in whole animals? YES  NO  If yes, describe constructions, transfer methods and the animal species involved.

5. Are animal or human pathogens involved? YES  NO  If NO go to Section C. below. If YES, what are these, what is their Center for Disease Control (CDC) classification and what pathogenic products may be produced? (The classification should be accurately reflect the CDC listing; report any toxins, virulence factors or viral products that may be produced.)

6. Will the pathogen itself be used as a recipient for any recombinant DNA? YES  NO  If YES, will any expression be attempted and how will this be achieved?

7. Do any experiments involve host/vector culture greater than 10 liters? YES  NO  If YES, how much?

**C. PERSONNEL INVOLVED IN THIS PROPOSED STUDY.**

1. Is the Principal Investigator experienced in recombinant DNA technology? YES  NO  If NO, how will experience be obtained? If YES, describe briefly what that is (reprints are acceptable and list one or two appropriate ones here).

2. List Name, Title, Department and Role on the Project of other individuals to be involved. (NOTE: the P.I. is responsible for their proper training.)

3. Where will the work be conducted on the TTUHSC campus?

4. Are there any collaborative arrangements directly involving recombinant DNA or its use?  
YES  NO  If YES, where and with whom?

5. Will work be conducted off the TTUHSC campus? YES  NO  If YES, where and with whom?

6. Will TTUHSC personnel conduct any of this work off campus? YES  NO  If YES, name these and describe the work and where it will take place.

**TTUHSC INSTITUTIONAL RECOMBINANT DNA BIOSAFETY ANNUAL REPORT**

**RENEWAL/AMENDMENT/TERMINATION**

**For Review by the Recombinant DNA Biosafety Committee (RDBC)**

*(Supporting NIH Reference Source: [http://www4.od.nih.gov/oba/rac/guidelines\\_02/NIH\\_Gdlines\\_2002prn.pdf](http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlines_2002prn.pdf))*

Please submit an original plus one copy (2 total) of this completed form to the OFFICE OF SPONSORED PROGRAMS (OSP), HSC Lubbock STOP 6271. This protocol expires \_\_\_\_\_. Return this form by \_\_\_\_\_.

PRINCIPAL INVESTIGATOR: \_\_\_\_\_

CAMPUS: \_\_\_\_\_

SCHOOL: \_\_\_\_\_

DEPARTMENT: \_\_\_\_\_

PHONE NO.: \_\_\_\_\_ EXT. \_\_\_\_

FAX NO.: \_\_\_\_\_

E-MAIL: \_\_\_\_\_

PROJECT TITLE: \_\_\_\_\_

\_\_\_\_\_ RENEWAL: Check only for the annual renewal of a currently active Registration. List the active OSP Registration Number \_\_\_\_\_.

\_\_\_\_\_ AMENDMENT: Check only for an amendment of a currently active Registration. List the active OSP Registration Number \_\_\_\_\_.

\_\_\_\_\_ TERMINATE: Check only for the termination of a currently active Registration. List the active OSP Registration Number \_\_\_\_\_.

**LIST DETAILS BELOW OF CHANGES FOR RENEWAL OR AMENDMENT**

\_\_\_\_\_ CHANGE: Materials or Procedures Involved in this Project

Delete:

Add:

\_\_\_\_\_ CHANGE: Personnel Involved in this Project

Delete:

Add:

\_\_\_\_\_ CHANGE: Location of Work Performed in this Project

Delete:

Add:

Principal Investigator Signature \_\_\_\_\_

**DO NOT WRITE BELOW THIS LINE – FOR RDBC COMMITTEE USE ONLY**

PROTOCOL: NUMBER: \_\_\_\_\_ DATE RECEIVED BY RDBC: \_\_\_\_\_

APPROVAL AND MINIMUM BIOLOGICAL AND PHYSICAL CONTAINMENT REQUIRED FOR THE TTUHSC PROPOSED STUDY UNDER NIH GUIDELINES

\_\_\_\_\_ EXEMPT \_\_\_\_\_ NONEXEMPT (\_\_\_ Physical and \_\_\_ Biological Containment)

CONTINUING REVIEW DUE: \_\_\_\_\_

Date

Signature of RDBC Representative